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September 15, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket No. 98N - 0313
RIN 0910 - AB74
Surgeon's and Patient Examination Gloves; Reclassification
Proposed Rule

To whom it may concern:

I am writing in regards to the proposed regulation to reclassify all surgeon and patient examination gloves to class II devices and set allowable limits of powder and protein in latex surgeon and examination gloves used for patients in the medical field. I would commend the proposed rule change as a "next good step" after the labeling requirement for latex containing products that went into effect September 30, 1998. However, there continues to be a number of problems that exist with the proposed ruling of which further work needs to continue.

First, the level of 1200 milligrams of protein in a glove is an unacceptably high level of protein and is only chosen due to the insensitivity of the proposed lab method of protein quantification. In addition, there is no attempt in this process to identify the allergenic protein and distinguish those proteins from non allergenic protein. This requires the use of specific immunologic assays and not the modified Lowry Test. The modified Lowry Test is insensitive and will allow unacceptably high levels of allergen to persist in latex gloves under this ruling. Since patients have reacted adversely in skin testing to levels of protein as low as one microgram or smaller, the allowance of 1200 milligram is excessive.

Second, the reduction of powder from 260 milligram (on average) to a 120 milligram is an unacceptably high level especially in light of the continued allowance of protein levels in the glove under this proposed rule. Data from Europe suggest that release of allergen into the air at levels of 0.6 nanograms per cubic meter of air is enough to invoke symptomatic disease in health care workers. This is clearly excessive powder to bind allergen and exceed levels that produce symptoms of latex allergy.

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Therefore, the continued work on quantitative immunologic assays and alternatives to powder as a lubricant for the donning of latex gloves is necessary and should be mandatory in the future. Although supportive of the overall attempt to place limits of powder and protein content of latex gloves, this rule must be looked at as merely a first step in reducing allergic reactions in the sensitized health care workers who are exposed to those materials.

Extending the proposed level of protein to latex materials other than gloves should be considered, especially for those latex products manufactured by a dipping process. In light of the majority of reactions reported to the Food and Drug Administration being related to allergic reactions from dipped latex products, extending this rule to those products makes good sense.

Although the mathematical discussion regarding reduction of risk of allergic reactions is clear, given the liberal new allowable limits of powder and protein in the gloves, the impact of this rule is likely to be overestimated. Since latex allergic patients adversely react below levels produced by the new standard, it is highly unlikely that the number of allergic reactions will be reduced until more drastic measures are imposed. The reduction in allergic reactions is unlikely to occur until a critical reduction (nondetection) in the level of allergen (not just protein) is achieved.

If my statements are not clear or I can be of further help in clarifying the issues, please feel free to contact me at (414) 266-6840.

Sincerely,

Kevin J. Kelly, M.D.
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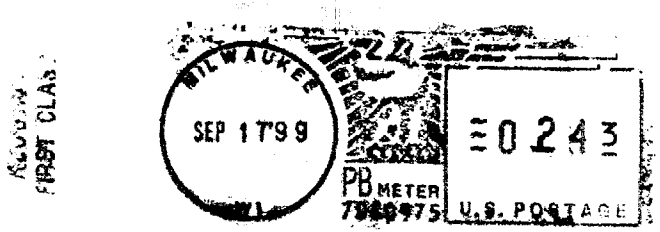

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